

THW

A35967 - 073226.0119 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants

Lee et al.

Serial No.

10/653,350

Examiner

Not Yet Assigned

Filed

September 2, 2003

Group Art Unit:

Not Yet Assigned

For

GLYCOSYLATED HUMAN INTERFERON ALPHA

Customer No.:

21003

INFORMATION DISCLOSURE STATEMENT

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

August 23, 2004

Date of Deposit

Carmella L. Stephens

41,328

Attorney Name

Patent Reg. No.

armella J. Stylla

Signature

Date of Signature

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §§1.97 and 1.98, applicants respectfully request that the documents listed below in reverse chronological order and on the accompanying PTO 1449 be considered

- by the Examiner and made of record in the above-referenced application. Copies of the documents listed are enclosed.
- 1. United States Patent No. 6,399,103 by Yamagata et al., entitled "Method of Producing a Sustained Release Preparation," issued June 4, 2002.
- 2. International Patent Application Publication No. WO 98/48840, entitled "Polyethylene Glycol-Interferon Alpha Conjugates for Therapy of Infection," published November 5, 1998.
- 3. Radhakrishnan et al., (1996)"Zinc mediated dimer of human interferon-α_{2b} revealed by X-ray crystallography", Structure vol.4, 1453-1463.
- 4. Adolf et al., (1991) "Natural human interferon-α2 is O-glycosylated", Biochem. J., 276 (Pt
 2), 511-518.
- 5. United States Patent No. 4,931,373 by Kawasaki et al., entitled "Stable DNA Constructs for Expression of α-1 Antitrypsin," issued June 5, 1990.
- Sambrook, J. Fritsch, E.F., Maniatis, T., (1989) Molecular Cloning A Laboratory Manual,
 2nd Edition, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, New York. (Table of Contents)
- 7. DeMaeyer and DeMaeyer-Guignard, (1988) Interferons and other regulatory cytokines, Wiley, New York. (Table of Contents)
- 8. Tovey et al. (1987) "Interferon messenger RNA is produced constitutively in the organs of normal individuals", Proc Natl Acad Sci USA, vol. 84, 5038-5042.
- 9. Pestka et al. (1982) "Interferons and their actions", Annu. Rev. Biochem., 56, 727-777.
- 10. Davis et al. (1986) Basic Methods in Molecular Biology, Elsevier Science Publishing Co.
- 11. Lengyel P. (1982) "Biochemistry of interferons and their actions", Annu. Rev. Biochem., 51,

NY02:472024.1 2

251-282.

- 12. Branca and Baglioni (1981) "Evidence that types I and II interferons have different receptors", Nature 294, 768-770.
- 13. Isaacs and Lindenmann (1957) "Virus interference. I. The interferon", National Institute for Medical Research, London, 258-267.

Identification of the listed documents is not to be construed as an admission of the applicants or attorneys for applicants that such citations are available as "prior art" against the subject application. If the Examiner applies the documents as prior art against any claim in the application and applicants determine that the cited documents do not constitute "prior art" under United States law, applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of the documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should the documents be applied against the claims of the present application.

3

NY02:472024.1

There should be no fee required for this submission. However, if any fee is required, or if any overpayment has been made, the Commissioner is hereby authorized to charge any fees, or credit or any overpayments made, to Deposit Account 02-4377. A duplicate copy of this paper is enclosed.

Respectfully submitted, BAKER BOTTS L.L.P.

Carmella L. Stephens PTO Reg. No. 41,328

30 Rockefeller Plaza 44th Floor New York, NY 10012-4498

Attorneys for Applicants (212) 408 2500

There should be no fee required for this submission. However, if any fee is required, or if any overpayment has been made, the Commissioner is hereby authorized to charge any fees, or credit or any overpayments made, to Deposit Account 02-4377. A duplicate copy of this paper is enclosed.

Respectfully submitted, BAKER BOTTS L.L.P.

Carmella L. Stephens PTO Reg. No. 41,328

30 Rockefeller Plaza 44th Floor New York, NY 10012-4498

Attorneys for Applicants (212) 408 2500

Form PTO- (REV. 2-82)			-		nt of C			•	Atty. Dočket No. A35967 – 073226.0119		Serial No. 10/653,350		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (See several sheets if necessary)									Applicants Lee et al. Filing Data Group Art Unit				
									Filing Date September 2, 2003		Group Art Unit Not Yet Assigned		
AUB 2 5 2	104 33 104 33 14	-						U.S. PATEN	T DOCUMENTS				
TANK & TRAU	NET C							Date	Name	Class	Subclass	Filing Date if Appropriate	
	6	3	9	9	1	0	.3	06/04/02	Yamagata et al.	424	489		
•	4	9	3 .	1	3	7	3	06/05/90	Kawasaki et al.	435	69.2		
,								FOREIGN PA	TENT DOCUMENT				
ş.		Document No.								Class	SubClass	<u>Translator</u>	
•	9	8	4	8	8	4	0	11/05/98	WO	Class	SubClass	Yes No	
										 	<u> </u>		
		Radhakrishnan et al., (1996)"Zinc mediated dimer of human interferon-α _{2b} revealed by X-ray crystallography", Structure vol.4, 1453-1463. Adolf et al., (1991) "Natural human interferon-α2 is <i>O</i> -glycosylated", Biochem. J., 276 (Pt 2), 511-518. Sambrook, J. Fritsch, E.F., Maniatis, T., (1989) Molecular Cloning A Laboratory Manual, 2nd Edition, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, New York. DeMaeyer and DeMaeyer-Guignard, (1988) Interferons and other regulatory cytokines, Wiley, New York. Tovey et al. (1987) "Interferon messenger RNA is produced constitutively in the organs of normal individuals", Proc Natl Acad Sci USA, vol. 84, 5038-5042. Pestka et al. (1982) "Interferons and their actions", Annu. Rev. Biochem., 56, 727-777. Davis et al. (1986) Basic Methods in Molecular Biology, Elsevier Science Publishing Co.											
		Lengyel P. (1982) "Biochemistry of interferons and their actions", Annu. Rev. Biochem., 51, 251-282. Branca and Baglioni (1981) "Evidence that types I and II interferons have different receptors", Nature 294, 768-770.											
								(1957) "Viru n, 258-267.	s interference. I. The interf	feron", N	Vational I	nstitute for	
Examiner								Date	Considered	<u></u>			

^{*} Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.